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Media Release

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Attorney General Announces 30-State Settlement with Bayer Corporation Bayer to Register and Post Results of Clinical Trials and Pay \$8 Million

Attorney General Joseph R. Biden, III today announced a settlement with Bayer Corporation over its marketing of Baycol, a drug used to lower cholesterol that was withdrawn from the market August 7, 2001. The settlement was part of a 30-state consumer protection enforcement action initiated by the states' Attorneys General due to concerns that Bayer failed to adequately disclose safety risks associated with Baycol.

The judgment, filed today in Superior Court, requires Bayer to register most of its clinical studies and then post the results at the end of each study. The judgment also demands Bayer's future compliance with the law in the marketing, sale and promotion of its pharmaceutical and biological products, and prohibits Bayer from making false and misleading claims relating to any such product sold in the United States. Significantly, the judgment further requires that Bayer pay a total of \$8 million to the 30 participating states, with Delaware and each of the participating states receiving \$200,000.

In May of 1998, Bayer introduced Baycol, a "statin" cholesterol-lowering drug, into the United States market. All statins carry a known risk of myopathy (a weakening of the muscles) and rhabdomyolysis (a more serious muscular disease). Through post-marketing surveillance of its product, Bayer learned that the risk for Baycol turned out to be significantly higher compared to other statins, particularly at higher doses and when combined with genfibrozil, another cholesterol-lowering drug. The Attorneys General allege that while Bayer informed the U.S. Food and Drug Administration about these adverse effects, Bayer failed to adequately warn prescribers and consumers about them. While Bayer denies any wrongdoing in the judgment, on August 7, 2001 Bayer voluntarily withdrew Baycol from the market.

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